DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region M3572N

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6008

WARNING LETTER

Certified Mail
Return Receipt Requested

File # 00-NWJ-25

March 22, 2000

William McCarthy
President
PEL Associates, Inc.
205 Meister Avenue
North Branch, NJ 08876

Dear Mr. McCarthy:

During the February 8 and 15, 2000 inspection of your facility, our investigator documented deviations from Current Good Manufacturing Practices (CGMP's) for Finished Pharmaceuticals (Code of Federal Regulations, Title 21, Part 211). These deviations cause your Aerozoin and Benzoin over-the-counter topical aerosol drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act. The deviations included:

- Failure to perform identity and purity testing following manufacture and packaging for each lot or batch of drug product. In addition, microbiological testing is not being performed on Aerozoin/Benzoin lots *[21 CFR 211.165(a) & (b)]*. Both products are labeled as antiseptic and anti-pruritic agents. This identical observation was previously reported to Mr. Robert Swiatecki, Vice President, in a Notice of Inspectional Observations (Form FDA-483) issued at the close of the previous inspection on June 3, 1998. Your firm promised to correct that deficiency.

- Failure of the quality control unit to perform batch record review of each lot or batch of drug product manufactured and packaged prior to release for distribution *[21 CFR 211.192]*.

- Failure to generate and implement standard operating procedures for: cleaning and maintenance of manufacturing equipment; employee training (including training in CGMP's); investigating and documenting out-of-specification results; in-process quality control tests; finished product testing; and complaints *[21 CFR 211.100(a)]*. Several of these deficiencies were cited to Mr. Swiatecki on the June 3, 1998 FDA-483. Corrections to the deficiencies were promised at the close of that inspection, but those deficiencies continue.

- Failure to investigate an over-production of 2,892 units of lot 8750 of Aerozoin using the formulation for a 30,000 theoretical unit batch. In addition, your firm has no validation data to support production of a batch containing more than 30,000 packaged units *[21 CFR 211.100(a) & (b)].*

- Failure to maintain the Certificates of Analysis for lots 4995000 and 489330 of Tincture of Benzoin, USP used in the manufacture of Aerozoin lots 8750 and 8460, respectively *[21 CFR 211.84(e)].*

The above deviations are not intended to be an all-inclusive list of violations. As a manufacturer of drug products for human use, you are responsible for assuring that your overall operation and the products you manufacture are in compliance with the law. It is your responsibility to assure adherence with each requirement of the Current Good Manufacturing Practice regulations. Federal agencies are advised of the issuance of all Warning Letters concerning drugs so that they may take this information into account when considering the award of contracts. Additionally, pending Antibiotic Form 6, New Drug Applications, Abbreviated New Drug Applications, or export approval requests may not be approved until the above violations are corrected.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and /or injunction.

You should notify this office in writing, within 15 working days upon receipt of this letter, of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to the Food and Drug Administration, Attention: Kirk D. Sooter, Compliance Officer, at the address and telephone number above.

Sincerely yours,

Douglas I. Ellsworth
District Director

Cc: EF (CFN 2245514; PEL Associates, Inc.)
Bcc: HFC-230
HFD-322
HFR-CE300 (DD)
HFR-CE340 (DCB / KDS / WL file)
HFR-CE350 (DIB / MJS / ALS)
HFI-35 (purged)
NWJ-DO Reading File